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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,980	09/20/2005	Naoya Satou	2005_0318A	5010
513 7590 08/16/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER SZNAIDMAN, MARCOS L	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 08/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,980

Applicant(s)

SATO, NAOYA

Examiner

Marcos L. Sznaidman

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/28/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-30 are currently pending and are the subject of this office action.

Claims 1-30 are currently under examination. This is the First Office Action on the Merits of the claims.

Priority

The present application claims priority to international application No. PCT/JP03/11010 filed 08/29/2003, and to foreign application No. JP 2002-255746 filed 08/30/2002.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The term "solvate" in claim 1 renders the claim indefinite. The term "solvate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Here the term "solvate" is considered indefinite

Art Unit: 1609

because there is no way to determine which particular solvent the applicant is referring to, among all possible choices.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

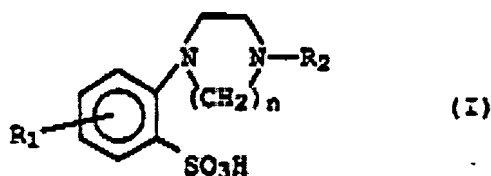
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-30 rejected under 35 U.S.C. 102(b) as being anticipated by Okushima et. al. (European Patent Publication No. 0390654, cited by applicant) or Okushima et. al. (U. S. patent No. 5,053,409).

Instant claims 1-30 describe a composition/medicament of the general formula I (see claim 1 of the instant application) and/or salts thereof, or a hydrate thereof or a solvate thereof. The statement in claims 1 to 14: "for suppressing intracellular excess accumulation of sodium ions" is considered an intended use, and is given little weight in examination. Similarly the statements in claims 15-16, 19-30: "for therapeutic and/or preventive treatment of", are considered an intended use, and are given little weight in examination. For claims 1-30, Okushima et. al. (EP0390654 or US 5,053,409) teaches a composition/medicament of the general formula I identical to formula I of the instant application.

Art Unit: 1609



wherein R_1 represents hydrogen atom, a $C_1 - C_6$ alkyl group, a $C_6 - C_7$ cycloalkyl group, a $C_1 - C_6$ halogenated alkyl group, a halogen atom or a $C_6 - C_{12}$ aryl group, R_2 represents hydrogen atom, a $C_1 - C_6$ alkyl group or a $C_7 - C_{12}$ alkyl group which may have at least one substituent selected from cyano group, nitro group, $C_1 - C_6$ alkoxy groups, halogen atoms, $C_1 - C_6$ alkyl groups and amino groups, and n represents an integer of 1 to 4, or a pharmaceutically acceptable salt thereof.

Okushima et. al. (EP0390654 or US 5,053,409) also teaches specific compounds (table I, pages 4-10 of EP0390654 or table I, pages 5-11 of US 5,053,409) that cover all the specific compounds described in the specification (Table 1, pages 6-13 of the instant application) and the remaining claims of the instant application.

Double Patenting

6. Claims 1-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/484,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim identical set of compounds (aminobenzenesulfonic acid derivatives). The instant claims and the claims of application No. 10/484,463 only differ regarding the recited intended use of these compounds ("for suppressing intracellular excess accumulation of sodium ions" in the instant application, vs. "for inhibiting sodium/calcium exchange system" in

Art Unit: 1609

application No. 10/484,463), and these intended uses are given little weight in examination. However, these intended uses describe the same effect that is to inhibit or suppressing intracellular excess accumulation of sodium ions, therefore the cited claims of the instant application and copending 10/484,463 are considered identical.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 10-20 of U.S. Patent No. 5,053,409. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim identical set of compounds (aminobenzenesulfonic acid derivatives). The instant claims and the claims of Patent No. 5,053,409 only differ that in the instant application, applicant discloses an intended use of these compounds ("for suppressing intracellular excess accumulation of sodium ions" in the instant application), and it is given little weight in examination.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcos L. Sznajdman whose telephone number is 571 270-3498. The examiner can normally be reached on Monday through Friday 9 AM to 5 PM.

Art Unit: 1609

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 9, 2007
MLS


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